

tives and assigns, and all persons in active concert or participation with him, be further perpetually enjoined

- (a) from participating, directly or indirectly, in the profits of the said Clinic through the lease contract with Harry R. Taylor after December 31, 1960, which said lease contract shall terminate on or before December 31, 1960, when said premises are vacated by Dr. Harry R. Taylor;
- (b) from the further operation of the Clinic at 4507 Gaston Avenue, or elsewhere, as the Hoxsey Cancer Clinic, Hoxsey Clinic, Taylor Clinic, and as any successor to any such Clinic.

"AND IT IS FURTHER ORDERED that the Clinic building and its equipment may be leased for legitimate medical or osteopathic practice, but only if it does not involve directly or indirectly in any way whatsoever the use of the Hoxsey treatment, being the drugs described in the Decree of October 26, 1953, or any similar drugs, and does not involve the lease or use of the patient records which have been built up through the operation of the Hoxsey Cancer Clinic, the Hoxsey Clinic, the Taylor Clinic, and Harry M. Hoxsey and his physician employees.

"AND IT IS FURTHER ORDERED that there be a complete and final discontinuation of the Hoxsey treatment, and that the said Harry M. Hoxsey shall so notify any person communicating with him about the said treatment."

6317. Hoxsey treatment for internal cancer. (Inj. No. 382). See also N.J. No. 6316 in this supplement.

COMPLAINT FOR INJUNCTION FILED: 9-16-60, N. Dist. Tex., against Harry R. Taylor, t/a Taylor Clinic, Dallas, Tex., and against Alan F. de Vore and Walter J. Williams, medical practitioners employed by Harry R. Taylor, to enjoin such parties against causing the *Hoxsey treatment for internal cancer* to be introduced and delivered for introduction into interstate commerce.

NATURE OF DRUGS: The complaint alleged that the essential part of the *Hoxsey treatment for internal cancer* was a liquid medicine, variously known as "Tonic Black" or "Liquid Tonic (Black)" or "Regular Tonic" or "Liquid Tonic," and labeled as "Concentrate Solution," and containing the following ingredients: Extract Cascara Sagrada, Potassium Iodide, Red Clover, Burdock Root, Alfalfa Leaf, Prickly Ash Bark, Water, Buckthorn Bark, Licorice, Stillingia Root, and Berberis Root; and that at times the essential part of the Hoxsey treatment had been compounded and dispensed in tablet form, known variously as "Calton Tablets," "Rx 100 Tablets" or "Hoxsey Tablets #100, S. C. Black," containing the following ingredients: Potassium Iodide, Licorice, Red Clover, Burdock Root, Stillingia Root, Berberis Root, Poke Root, Extract Cascara Sagrada Aromatic, U. S. P. XIV, Prickly Ash Bark, and Buckthorn Bark. It was also alleged that if a patient could not tolerate the "Liquid Tonic (Black)" another liquid medicine was substituted for it, and that such liquid medicine was labeled as "Concentrate Solution" and variously known as "Red Tonic" or "Lactate Red Solution" or "Lactate Liquid" or "Lactate (Red)," containing the following ingredients: Potassium Iodide, Red Clover, Burdock Root, Alfalfa Leaf, Prickly Ash Bark, Elixir Lactated Pepsin, Buckthorn Bark, Stillingia Root, and Berberis Root; and that at times such alternative form of the Hoxsey treatment had been compounded and dispensed in tablet form known variously as "Lactabs" or "Lactabs, S. C. Red" or "Lactate Tablets," containing the ingredients Potassium Iodide, Red Clover, Stillingia Root, Berberis Root, Poke Root, Buckthorn Bark, and Pepsin.

ACCOMPANYING LABELING: Leaflets entitled "Instructions for Melanomas, Hodgkins Disease, Leukemias, and Lympho-Sarcoma," "Instructions For Bone

Spread," "Instructions For Lung Cases," "Instructions For Tongue, Mouth and Throat Cases," "Instructions for Breast Cases," "Instructions For Bleeding," "Instructions For Uterus Cases," "Instructions For Stomach and Intestines Cases," and "Instructions for Rectal Involvement," and a book entitled "You Don't Have To Die."

METHOD OF OPERATION: The complaint alleged that the defendants operated in the following manner in the sale of the Hoxsey treatment:

(a) Persons suffering from cancer, persons who believed they had cancer, and others hoping to prevent cancer or recurrence thereof, were induced to visit the Taylor Clinic for the purpose of obtaining the *Hoxsey treatment for internal cancer*, because of the widespread circulation of the book entitled "You Don't Have To Die" by Harry M. Hoxsey, and because of articles in magazines, including the Defender Magazine, the Herald of Health Magazine, and The National Health Federation Bulletin lauding the Hoxsey treatment;

(b) In response to inquiries from such persons living outside the State of Texas, concerning the *Hoxsey treatment for internal cancer*, invitations to visit the Taylor Clinic, Dallas, Tex., were issued in letters bearing the signature of defendant Harry R. Taylor, or defendant H. W. Crawford, as "Administrator" of the Taylor Clinic;

(c) When the prospective out-of-state customers arrived at the said Taylor Clinic at Dallas, Tex., they were interviewed by the defendants and employees;

(d) A discussion at such interview of the prospective customers' symptoms and ailments was followed by laboratory tests of blood and urine, X-rays and physical examinations. On this basis the prospective customers' conditions were diagnosed as cancer. Biopsies were not made by the defendants in arriving at such diagnoses; and

(e) The customers were then sold the *Hoxsey treatment for internal cancer*, comprised essentially of the liquid tonic or the equivalents thereof, together with so-called supportive medications including vitamin preparations, laxatives, kidney pills, pain pills and the like. The treatment was delivered to the customer for transportation outside the State of Texas, with written instructions on its use.

The complaint also alleged that Harry R. Taylor, t/a Taylor Clinic, was associated with Harry M. Hoxsey pursuant to the terms of a lease agreement signed by Harry M. Hoxsey and Harry R. Taylor on April 13, 1957, and supplemented by an agreement signed by such parties on May 1, 1957, whereby the said Harry M. Hoxsey, as lessor, agreed, among other things, to lease to said Harry R. Taylor, the lessee, the premises occupied by the Hoxsey Cancer Clinic, a partnership, at 4507 Gaston Avenue, Dallas, Tex., and certain furniture, equipment, patients' files and medical records for the term of five years beginning on May 1, 1957, and Harry R. Taylor agreed, among other things, to pay to Harry M. Hoxsey a minimum rent of \$2,500 per month, plus additional rent equal to 50 percent of the net profits from the use and occupancy of said premises by said Harry R. Taylor less the \$2,500 minimum monthly rental.

CHARGE: The complaint alleged that the defendants were engaged in promoting, selling, distributing, and causing to be introduced and delivered for introduction into interstate commerce the above-described *Hoxsey treatment for internal cancer* which was misbranded as follows: 502(a)—the article was accompanied by the above labeling which falsely represented and suggested that the *Hoxsey treatment for internal cancer* was adequate and effective in

the treatment and prevention of internal cancer in man; 502(f) (1)—at times, no labeling accompanied the article in which case the labeling of the article failed to bear adequate directions for use in that its labeling failed to state the condition or disease, namely, cancer, which the article was intended to treat or prevent; 502(f) (1)—with or without the above labeling, the article failed to bear labeling stating adequate directions for use in that the directions as to the dosage and frequency and duration of administration were not adequate for the treatment or prevention of the disease and condition for which the article was intended, namely, cancer, since the article was worthless for the treatment or prevention of cancer and adequate directions could not be given for the use of the article in the treatment or prevention of such disease or condition.

The complaint alleged also that the *Hoxsey treatment for internal cancer* had been adjudged worthless for the treatment of cancer in man on 3 previous occasions resulting in:

(a) a decree of permanent injunction, dated 10-26-53, issued by the United States District Court for the N. Dist. Tex. (See D.D.N.J. No. 4654);

(b) a decree of condemnation pursuant to a jury verdict returned on 11-16-56 in the United States District Court for the W. Dist. Pa. (See D.D.N.J. No. 5212); and

(c) an injunction decree entered on 10-2-57 in the United States District Court for the W. Dist. Pa. (See D.D.N.J. No. 5202).

DISPOSITION: On 9-16-60, the United States District Court for the Northern District of Texas entered the following consent decree of permanent injunction:

ESTES, *District Judge*: "The United States of America, having filed its complaint on the 16th day of September, 1960, and the defendants, Harry R. Taylor, an individual, trading as Taylor Clinic, and Alan F. de Vore, Walter J. Williams, individuals, having appeared and having consented to the entry of this decree without contest and before any testimony has been taken, and the United States of America having consented to the entry of this decree and to each and every provision thereof, and having moved this Court for this injunction;

"WHEREFORE, IT IS ORDERED, ADJUDGED, AND DECREED, as follows:

"1. That the Court has jurisdiction of the subject matter herein and of all persons or parties hereto and the complaint states a cause of action against the defendants under the Federal Food, Drug, and Cosmetic Act;

"2. That the defendants, Harry R. Taylor, an individual, trading as Taylor Clinic, and Alan F. de Vore, Walter J. Williams, individuals, and their agents, servants, employees, representatives, and all persons in active concert or participation with them or any of them be perpetually enjoined and restrained from directly or indirectly introducing or causing to be introduced or delivering or causing to be delivered for introduction into interstate commerce, and more particularly delivering or causing to be delivered to any patient or customer at said Clinic, in violation of section 301(a) of said Act [21 U.S.C. 331 (a)] the articles of drug known as the Hoxsey treatment for internal cancer, and any similar articles of drug, the labeling of which represents or suggests that the said drugs comprise the Hoxsey treatment for internal cancer in man, and any other drugs of similar composition which

(a) are accompanied by labeling, namely, the leaflets entitled 'Instructions for Melanomas, Hodgkin's Disease, Leukemias, and Lympho-Sarcoma,' 'Instructions for Bone Spread,' 'Instructions for Lung Cases,' 'Instructions for Tongue, Mouth and Throat Cases,' 'Instructions for Breast Cases,' 'Instructions for Bleeding,' 'Instructions for Uterus Cases,' 'Instructions for Rectal Involvement,' 'Instructions for Stomach and Intestines Cases,' and the book entitled 'You Don't Have To Die';

(b) are represented or suggested in their labeling to be adequate and effective in the treatment of cancer in man;

- (c) bear or are accompanied by labeling containing any false or misleading representations or suggestions;
- (d) bear or are accompanied by labeling containing inadequate directions for the use of said articles in the treatment and prevention of cancer; or
- (e) fail to bear or be accompanied by labeling containing the name of the disease or condition for which said articles are intended to be used, namely, cancer.

"3. That the defendants, their agents, servants, employees, representatives, and all persons in active concert or participation with them or any of them shall discontinue immediately all distribution of the so-called Hoxsey cancer treatment, and shall notify immediately all persons shown by the defendants' files to have purchased the treatment since May 1, 1957, as well as all new patients coming to the said Clinic for treatment

- (a) that the distribution of the treatment has been enjoined by order of this Court;
- (b) that the treatment no longer may be obtained at the Taylor Clinic; and
- (c) that the defendants will be in criminal contempt of this Court by delivering said treatment to any person at the said Clinic or elsewhere.

"4. That the defendants are prohibited from using or distributing the so-called Hoxsey cancer treatment under the guise of practicing medicine or osteopathy since the use of that treatment is no part of the practice of medicine or osteopathy.

"5. That the defendants shall provide free access to the said Clinic, and to all the drugs, labeling, promotional material, patient correspondence, and all other records therein, in order that the inspectors of the Food and Drug Administration may determine that the prohibitions and requirements of this decree are being fully observed.

"6. That jurisdiction of this Court is retained for the purpose of enforcing or modifying this decree and for the purpose of granting such additional relief as may hereinafter appear necessary or appropriate.

"7. That this decree shall not be construed as an admission by the defendants that they have been guilty of the wrongful acts as alleged in the complaint filed by Plaintiff."

6318. Reviv-A-Tone and Thermal Heat Massage device. (F.D.C. No. 44586. S. No. 11-576 R.)

QUANTITY: 10 devices at Chicago, Ill.

SHIPPED: 5-8-60, from Allen Park, Mich., by Hel-Mac Distributing Co.

LABEL IN PART: "Reviv-A-Tone Health Unit."

ACCOMPANYING LABELING: Leaflets entitled "Reviv-A-Tone and Thermal Heat."

RESULTS OF INVESTIGATION: The article was a semi-rigid, pillow type, electric vibrator device. In addition to the vibrating motor, the device contained an electric heating element.

LIBELED: 5-19-60, N. Dist. Ill.

CHARGE: 502(a)—when shipped and while held for sale, the labeling which accompanied the article contained false and misleading representations and suggestions that the article was an adequate and effective treatment for relieving periodic cramps; lower backaches; and nervous tension; spot reducing and aiding circulation; reducing hips, thighs, and flabby muscles in the abdominal region; and 502(f) (1)—its labeling failed to bear adequate directions for use in the treatment of migraine headaches, nervous tension, bursitis, arthritis, varicose veins, rheumatism, hardening of the arteries, ulcers, and chest colds, which were the conditions for which the article was orally offered by Mr. John M. McFarland, a representative of the Hel-Mac Distributing Co.

DISPOSITION: 7-27-60. Default—delivered to Food and Drug Administration.